



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1006]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with reports of removals and corrections for medical and radiation emitting products regulated by FDA's Center for Devices and Radiological Health.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-1006 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Reports of Corrections and Removals." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Reports of Corrections and Removals--21 CFR part 806

OMB Control Number 0910-0359--Revision

This information collection supports implementation of provisions of section 519(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(g)) requiring device manufacturers and importers to report promptly to FDA certain actions concerning device corrections and removals and to maintain associated records. Applicable regulations are found in 21 CFR part 806 and set forth definitions, prescribe format and required content elements for reporting, and identify actions that are exempt from the reporting requirements. The information collected is

used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. The information also helps ensure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate.

Reports of corrections and removals may be submitted to FDA via mail, email, or using FDA’s Electronic Submission Gateway (ESG). To assist respondents with submitting reports of corrections or removals, we developed a fillable PDF electronic submission template entitled, “Device Correction/Removal Report for Industry,” that transmits required data to FDA’s Recall Enterprise System. Instructions for the fillable template are provided in pop-up text boxes that appear over each data field. We expect that use of the fillable template will expedite processing of the reports of corrections or removals submitted to FDA.

We estimate the burden of the information collection as follows:

Table 1--Estimated Annual Reporting Burden

21 CFR Part; Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
Electronic process setup	517	1	517	3.08	1,592	\$25,850
806; Submission of corrections and removals	1,033	1	1,033	10	10,330	
4.102(c)(1)(iii); Submitting correction or removal reports	20	1	20	10	200	
Total						\$25,850

For respondents who submit corrections and removals using the ESG, the operating and maintenance costs associated with this information collection are approximately \$50 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be reduced if the respondent has already purchased a verification certificate for other electronic submissions to FDA. This burden may also be reduced if respondents utilize the new PDF template and submit it to the Agency using email, mitigating the need for a digital verification certificate.

Table 2--Estimated Annual Recordkeeping Burden^{1,2}

21 CFR Part; Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
806; Records of corrections and removals	93	1	93	10	930
4.105(b); recordkeeping by device-led combination products	279	1	279	0.5 (30 minutes)	140
Total					1070

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Figures have been rounded.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We estimate that 50 percent of submitters will use the ESG to submit the required information. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG. For the purposes of estimating the burden, we assume that all respondents who submit corrections and removals using the electronic process will establish a new WebTrader account and purchase a digital verification certificate.

Dated: April 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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